

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI**

ELSIE ALICE BUEHLER,

Plaintiff,

v.

ZIMMER, INC.; ZIMMER HOLDINGS,  
INC.; AND ZIMMER ORTHOPAEDIC  
SURGICAL PRODUCTS, INC.

Defendants.

Court File No. 4:11-cv-1016

**COMPLAINT -  
JURY TRIAL DEMAND**

Plaintiff, by their attorneys, **SCHLICHTER BOGARD & DENTON** and **DOUGLAS & LONDON, P.C.**, upon information and belief, at all times hereinafter, alleges as follows:

**NATURE OF THE CASE**

1. This is an action for damages suffered by ELSIE ALICE BUEHLER, as a direct and proximate result of Defendants' wrongful conduct in connection with the development, design, manufacture, distribution, and selling of Defendants' knee replacement product, the Zimmer NexGen total knee replacement system, including the Zimmer NexGen LPS (hereinafter "Zimmer NexGen Knee")

2. Defendants knew or should have known that the Zimmer NexGen Knee can loosen in patients, such as Plaintiff, causing personal injury, significant pain, and loss of movement, and that this injury can only be remedied through subsequent revision surgery and/or knee replacement. Further, Defendants misinformed health care professionals and the public into believing that the Zimmer NexGen Knee was safe and effective for use in knee replacement surgery; engaged in deceptive, misleading and false promotional or sales methods to convince health care professionals to utilize the Zimmer NexGen Knee, even though Defendants knew or

should have known that the Zimmer NexGen Knee was unreasonably unsafe; and failed to warn health care professionals and the public about the safety risks of the Zimmer NexGen Knee.

### **PARTIES**

3. Plaintiff ELSIE ALICE BUEHLER is a citizen of the State of Missouri, and a resident of Columbia.

4. Defendant Zimmer, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business located in Warsaw, Indiana.

5. Defendant Zimmer Holdings, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business located in Warsaw, Indiana.

6. Defendant Zimmer Orthopaedic Surgical Products, Inc. is a corporation organized and existing under the laws of Ohio, and has its principal place of business in Dover, Ohio.

7. Defendants Zimmer Inc., Zimmer Holdings, Inc. and Zimmer Orthopaedic Surgical Products, Inc. are collectively referred to as “Defendants.”

8. At all times material hereto, Defendants developed, designed, tested, manufactured, distributed, marketed, and sold the Zimmer NexGen Knee. Defendants’ products, including the Zimmer NexGen Knee, are sold throughout the world, including within the State of Missouri.

### **JURISDICTION AND VENUE**

9. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds \$75,000 exclusive of interest and costs.

10. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. § 1391(a), as a substantial number of the events, actions or omissions giving rise to Plaintiff’s

claims occurred in this district. At all times material hereto, Defendants conducted substantial business in this district.

**FACTUAL BACKGROUND**  
**KNEE REPLACEMENT BACKGROUND**

11. Total Knee Arthroplasty (“TKA”), also called total knee replacement, is a common medical procedure performed. The surgery is designed to help relieve pain and improve joint function in people with severe knee degeneration due to arthritis or trauma.

12. Upon information and belief, the TKA procedure is done by separating the muscles and ligaments around the knee to expose the inside of the joint. The ends of the thigh bone (femur) and the shin bone (tibia) are removed as is often the underside of the kneecap (patella).

13. Upon information and belief, about 85 to 90 percent of total knee replacements are successful up to ten years.

14. *Mechanical loosening* means that for some reason (other than infection) the attachment between the artificial knee and the bone has become loose.

15. Loosening can occur with any component of the artificial knee: the femoral, the tibial or the patellar component.

16. Upon information and belief, loosening of an artificial knee can be diagnosed using X-ray images that show one or more radiolucent lines around the contours of the artificial knee joint.

17. A loose artificial knee is a problem because it causes pain and wearing away of the bone. A painful loose knee can restrict the patient’s daily activities severely. A loose artificial knee also involves severe psychological burden for the patient.

18. Once the pain becomes unbearable or the individual loses function of the knee, another operation may be required to revise the knee replacement. A loose, painful artificial knee can usually, but not always, be replaced.

19. The purpose of knee revision surgery is to remove a failed knee implant and replace it with a new one.

20. Upon information and belief, a revision operation of a failed knee implant is problematic because the surgeon must reconstruct the severe bone loss caused by bone destruction around the failed total knee prosthesis, and restore the stability in the revised total knee.

21. Upon information and belief, the results of a revision operation are not as good as the first, and the risks of complications are higher. The range of motion in the knee after revision surgery may be reduced and the walking capacity may also be diminished. The rate of loosening increases after revision surgery.

#### **ZIMMER NEXGEN KNEE FACTS**

22. Zimmer was founded in 1927, and purports to be a worldwide leader in the design and manufacture of orthopaedic reconstructive, spinal and trauma devices, dental implants, and related orthopaedic surgical products.

23. Some Zimmer NexGen Knees use a “high-flex” femoral component that purports to allow a greater degree of flexion than the standard femoral component.

24. The Defendants generally, manufactured, labeled, packaged, distributed, supplied, marketed, advertised, and/or otherwise engaged in all activities that are part and parcel of the sale and distribution of a pharmaceutical, and by said activities, caused the Zimmer NexGen Knee to be placed into the stream of commerce throughout the United States.

25. Defendants made, participated in and/or contributed to filings with the FDA in conjunction with the approval process for the Zimmer NexGen Knee.

26. Upon information and belief, Defendants were in control of the design, assembly, manufacture, marketing, distribution, packaging, labeling, processing, supplying, promotion, sales, and the issuance of product warnings and related information with respect to the Zimmer NexGen Knee.

27. Defendants were at all times material hereto subject to the laws of the United States of America, including provisions relating to the FDA, and the rules and regulations thereof, in conjunction with the approval process, labeling, and other after-market activities that pertain to the Zimmer NexGen Knee.

28. The Zimmer NexGen Knee has been widely advertised, marketed and represented by the Defendants as a safe and effective treatment.

#### **ZIMMER NEXGEN KNEE PROBLEMS**

29. Studies show that a knee implant that allows for higher flexation, like the Zimmer NexGen Knee, is more likely to fail because higher flexation places the knee implant at a higher risk of loosening.

30. Additionally, The Journal of Bone and Joint Surgery (British Edition) published a peer reviewed study by professors at the Seoul National University College of Medicine in 2007 titled, *High Incidence of Loosening of the Femoral Component in the Legacy Posterior Stabilised-Flex Total Knee Replacement*. The study showed that 38% of the implanted LPS high flex knees were loose shortly after 2 years post implant. From the group of patients with loose knees, over half (56%) had their knee revised due to pain.

31. From the time that Defendants first began selling the Zimmer NexGen Knee in the United States, the product labeling and product information for the Zimmer NexGen Knee failed to contain adequate information, instructions, and warnings concerning implantation of the product and the increased risks that the Zimmer NexGen Knee can loosen in patients.

32. Despite its knowledge of the serious injuries associated with using the Zimmer NexGen Knee, Defendants engaged in a marketing and advertising program which as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that using the Zimmer NexGen Knee was safe.

33. Upon information and belief, Defendants downplayed and understated the health hazards and risks associated with the use of the Zimmer NexGen Knee and through promotional literature as well as sales visits to orthopaedic surgeons, deceived doctors and potential users of the Zimmer NexGen Knee by relaying positive information, while concealing the nature and extent of known adverse and serious health effects.

### **FACTUAL ALLEGATIONS**

34. On June 6, 2006, Plaintiff's physician implanted a Zimmer NexGen Knee system into Plaintiff.

35. Upon information and belief, prior to June 6, 2006, the treating physician for Plaintiff, as well as Plaintiff, was exposed to the aforementioned advertising and marketing campaign directly by the Defendants.

36. Plaintiff and Plaintiff's physician, either through direct promotional contact with Defendants' sales force, through word-of-mouth from other health care providers, and/or through promotional materials, received the information the Defendants intended that they receive, to-wit: that the Zimmer NexGen Knee was safe and effective for use in TKA procedures.

37. Plaintiff began experiencing severe and debilitating pain shortly after implant.

38. Plaintiff returned to Plaintiff's physician several times due to consistent pain in her knee.

39. In May 2008, Plaintiff had a second surgery to revise/replace her previously implanted Zimmer NexGen Knee because of loosening. Plaintiff's entire artificial knee system was replaced. Plaintiff was never told, by any source, that her knee failed because the product itself was defectively designed.

40. As a direct and proximate result of the use of the Zimmer NexGen Knee, Plaintiff suffered, and continues to suffer, serious bodily injury and harm.

41. As a direct and proximate result of the use of the Zimmer NexGen Knee, Plaintiff incurred, and continues to incur, medical expenses to treat her injuries and condition.

42. At no time material to her use of the Zimmer NexGen Knee was Plaintiff or her physicians told, warned, or given information about the higher risks of loosening in the Zimmer NexGen Knee.

**FIRST CAUSE OF ACTION  
AS AGAINST DEFENDANTS  
(NEGLIGENCE AND NEGLIGENCE PER SE)**

43. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

44. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Zimmer NexGen Knees into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

45. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of the Zimmer NexGen Knees into interstate commerce in that Defendants knew or should have known that using Zimmer NexGen Knees placed users at risk for developing serious and dangerous side effects including but not limited to, severe pain mechanical loosening and/or a knee revision surgery, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

46. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

- a. Manufacturing, producing, promoting, formulating, creating, and/or designing Zimmer NexGen Knees without thoroughly testing them;
- b. Manufacturing, producing, promoting, formulating, creating, and/or designing Zimmer NexGen Knees without adequately testing them;
- c. Not conducting sufficient testing programs to determine whether or not the aforesaid Zimmer NexGen Knees were safe for use; in that Defendants herein knew or should have known that Zimmer NexGen Knees were unsafe and unfit for use by reason of the dangers to its users;
- d. Selling the Zimmer NexGen Knees without making proper and sufficient tests to determine the dangers to its users;
- e. Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and/or the FDA of the dangers of Zimmer NexGen Knees;
- f. Negligently failing to recall its dangerous and defective Zimmer NexGen Knees at the earliest date that it became known that said Zimmer NexGen Knees were, in fact, dangerous and defective;
- g. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and



foreseeably come into contact with, and more particularly, use, Zimmer NexGen Knees;

- h. Failing to test the Zimmer NexGen Knees and/or failing to adequately, sufficiently and properly test Zimmer NexGen Knees.
- i. Negligently advertising and recommending the use of the aforesaid Zimmer NexGen Knees without sufficient knowledge as to its dangerous propensities;
- j. Negligently representing that said Zimmer NexGen Knees were safe for use for their intended purpose, when, in fact, they were unsafe;
- k. Negligently representing that the use of Zimmer NexGen Knees had equivalent safety and efficacy as other artificial knees;
- l. Negligently designing the Zimmer NexGen Knees in a manner which was dangerous to their users;
- m. Negligently manufacturing Zimmer NexGen Knees in a manner which was dangerous to their users;
- n. Negligently producing the Zimmer NexGen Knees in a manner which was dangerous to their users;
- o. Negligently assembling Zimmer NexGen Knees in a manner which was dangerous to their users;
- p. Concealing information concerning tests, and/or reports, and/or studies from the Plaintiff in knowing that the Zimmer NexGen Knees were unsafe, dangerous, and/or non-conforming with accepted industry standards;
- q. Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, and/or the public, concerning the severity of risks and dangers of Zimmer NexGen Knees.
- r. Defendants violated statutes, rules and ordinances concerning the manufacturing, marketing, and/or testing of their product.

47. Defendants under-reported, underestimated and downplayed the serious danger of Zimmer NexGen Knees.

48. Defendants negligently compared the safety risk and/or dangers of the use of Zimmer NexGen Knees to that of other artificial knees.

49. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of the Zimmer NexGen Knees in that they:

- a. Failed to use due care in designing and manufacturing of Zimmer NexGen Knees so as to avoid the aforementioned risks to individuals when the Zimmer NexGen Knees were used for their intended purpose;
- b. Failed to accompany their product with proper warnings regarding all possible adverse side effects associated with the use of the Zimmer NexGen Knees;
- c. Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;
- d. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Zimmer NexGen Knees;
- e. Failed to warn Plaintiff, prior to actively encouraging the sale of the Zimmer NexGen Knees, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and
- f. Were otherwise careless and/or negligent.

50. Despite the fact that Defendants knew or should have known that the Zimmer NexGen Knees caused unreasonably dangerous side effects, Defendants continued to market, manufacture, distribute and/or sell Zimmer NexGen Knees to consumers, including the Plaintiff.

51. Defendants' actions, by violating statutes, ordinances and/or rules and regulations, constituted negligence per se.

52. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury, and/or be at increased risk of suffering injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

53. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss which they suffered and/or will continue to suffer.

54. By reason of the foregoing Plaintiff ELSIE ALICE BUEHLER experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, severe pain, mechanical loosening and/or a knee revision surgery, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

55. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

56. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**SECOND CAUSE OF ACTION  
AS AGAINST DEFENDANTS  
(STRICT PRODUCTS LIABILITY)**

57. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

58. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed Zimmer NexGen Knees as hereinabove described that were used in the Plaintiff.

59. That Zimmer NexGen Knees were expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

60. At those times, the Zimmer NexGen Knees were in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, Plaintiff ELSIE ALICE BUEHLER.

61. The Zimmer NexGen Knees designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the aforesaid Zimmer NexGen Knees.

62. At all times herein mentioned, the Zimmer NexGen Knees were in a defective condition and unsafe, and Defendants knew or had reason to know that said products were

defective and unsafe, especially when used in the form and manner as provided by the Defendants.

63. Defendants knew, or should have known, that at all times herein mentioned their Zimmer NexGen Knees were in a defective condition, and were and are inherently dangerous and unsafe.

64. At the time of the implantation of the Zimmer NexGen Knees into Plaintiff, the aforesaid products were being used for the purposes and in a manner normally intended.

65. Defendants with this knowledge voluntarily designed their Zimmer NexGen Knees in a dangerous condition for use by the public, and in particular the Plaintiff, ELSIE ALICE BUEHLER.

66. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

67. The Zimmer NexGen Knees designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were manufactured defectively in that said products left the hands of Defendants in a defective condition and were unreasonably dangerous to their intended users.

68. The Zimmer NexGen Knees designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' products were manufactured.

69. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the

health of consumers and to Plaintiff, ELSIE ALICE BUEHLER, in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

70. The Plaintiff could not, by the exercise of reasonable care, discover the defective nature the Zimmer NexGen Knees herein mentioned and perceived its danger.

71. The Zimmer NexGen Knees designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including but not limited to severe pain mechanical loosening and/or a knee revision surgery, and/or other severe and permanent health consequences.

72. The Zimmer NexGen Knees designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings and/or inadequate testing.

73. The Zimmer NexGen Knees designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including but not limited to severe pain, mechanical loosening and/or a knee revision surgery and/or other severe and permanent health consequences.

74. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of defective products, the Zimmer NexGen Knees.

75. Defendants' defective design, manufacturing defect, and inadequate warnings of the Zimmer NexGen Knees were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

76. By reason of the foregoing Plaintiff ELSIE ALICE BUEHLER has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, severe pain, mechanical loosening and/or a knee revision surgery, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

77. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

78. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**THIRD CAUSE OF ACTION  
AS AGAINST ALL DEFENDANTS  
(BREACH OF EXPRESS WARRANTY)**

79. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

80. Defendants. expressly warranted that Zimmer NexGen Knees were safe and well accepted by users.

81. The Zimmer NexGen Knees do not conform to these express representations because they are not safe and they have numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer, and/or is at increased risk to suffer severe and permanent personal injuries, harm and/or economic loss.

82. Plaintiff did rely on the express warranties of the Defendants herein.

83. Members of the medical community, including physicians and/or other healthcare professionals, relied upon the representations and warranties of the Defendants for use of the Zimmer NexGen Knees in recommending and/or dispensing the Zimmer NexGen Knees.

84. The Defendants herein breached the aforesaid express warranties, as their Zimmer NexGen Knees were defective.

85. Defendants expressly represented to Plaintiff, and/or her physicians, healthcare providers that the Zimmer NexGen Knees were safe and fit for use for the purposes intended, that they were of merchantable quality, that they did not produce any dangerous side effects in excess of those risks associated with other prosthetic knees and that the side effects they did produce were accurately reflected in the warnings and that they were adequately tested and fit for their intended use.

86. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that the Zimmer NexGen Knees and/or were not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

87. By reason of the foregoing Plaintiff ELSIE ALICE BUEHLER has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to,



severe pain, mechanical loosening and/or a knee revision surgery, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

88. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

89. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**FOURTH CAUSE OF ACTION  
AS AGAINST ALL DEFENDANTS  
(BREACH OF IMPLIED WARRANTIES)**

90. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

91. At all times herein mentioned, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold the Zimmer NexGen Knees.

92. At the time Defendants marketed, sold, and distributed the Zimmer NexGen Knees products for use by Plaintiff, Defendants knew of the use for which the Zimmer NexGen Knees were intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

93. Defendants impliedly represented and warranted to the users of the Zimmer NexGen Knees and/or their physicians, healthcare providers, and/or the FDA that the Zimmer NexGen Knees were safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

94. That said representations and warranties aforementioned were false, misleading, and inaccurate in that the Zimmer NexGen Knees were unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

95. Plaintiff and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

96. Plaintiff and/or her physicians and/or healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether the Zimmer NexGen Knees were of merchantable quality and safe and fit for its intended use.

97. The Zimmer NexGen Knees were injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

98. The Defendants herein breached the aforesaid implied warranties, as their Zimmer NexGen Knees were not fit for their intended purposes and uses.

99. By reason of the foregoing Plaintiff ELSIE ALICE BUEHLER has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, severe pain, mechanical loosening and/or a knee revision surgery, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish,

including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

100. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

101. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**FIFTH CAUSE OF ACTION  
AS AGAINST ALL DEFENDANTS  
(FRAUDULENT MISREPRESENTATION)**

102. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

103. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff and/or the FDA, and/or the public in general, that said products, the Zimmer NexGen Knees had been tested and were found to be safe and/or effective.

104. That representations made by Defendants were, in fact, false.

105. When said representations were made by Defendants, they knew those representations to be false and they willfully, wantonly and recklessly disregarded whether the representations were true.

106. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in

particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense and/or purchase said products, the Zimmer NexGen Knees, for use as an artificial knee prosthesis, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff.

107. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff used the Zimmer NexGen Knees, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

108. In reliance upon said representations, the Plaintiff was induced to and did use the Zimmer NexGen Knees, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

109. Said Defendants knew and were aware or should have been aware that the Zimmer NexGen Knees had not been sufficiently tested, were defective in nature, and/or that they lacked adequate and/or sufficient warnings.

110. Defendants knew or should have known that the Zimmer NexGen Knees had a potential to, could, and would cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

111. Defendants brought the Zimmer NexGen Knees to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

112. By reason of the foregoing Plaintiff ELSIE ALICE BUEHLER has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, severe pain, mechanical loosening and/or a knee revision surgery, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish,

including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

113. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

114. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**SIXTH CAUSE OF ACTION  
AS AGAINST ALL DEFENDANTS  
(FRAUDULENT CONCEALMENT)**

115. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

116. At all times during the course of dealing between Defendants and Plaintiff and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of the Zimmer NexGen Knees for their intended use.

117. Defendants knew or were reckless in not knowing that its representations were false.

118. In representations to Plaintiff and/or Plaintiff's healthcare providers and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

- a. That Zimmer NexGen Knees are not as safe as other available artificial knees;
- b. That the risks of adverse events with the Zimmer NexGen Knees were higher than those with other available artificial knees;
- c. That the risks of adverse events with Zimmer NexGen Knees were not adequately tested and/or known by Defendants;
- d. Plaintiff was put at risk of experiencing serious and dangerous side effects including but not limited to, severe pain, mechanical loosening and/or a knee revision surgery as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish;
- e. That patients needed to be monitored more regularly than normal while using the Zimmer NexGen Knees;
- f. That the Zimmer NexGen Knees were manufactured, marketed, produced, and distributed negligently;
- g. That the Zimmer NexGen Knees were manufactured, marketed, produced, and distributed defectively;
- h. That the Zimmer NexGen Knees were manufactured, marketed, produced, and distributed improperly;
- i. That the Zimmer NexGen Knees were designed negligently;
- j. That the Zimmer NexGen Knees were designed defectively;
- k. That the Zimmer NexGen Knees were designed improperly.

119. Defendants were under a duty to disclose to Plaintiff and/or her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of the Zimmer NexGen Knees.

120. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used the Zimmer NexGen Knees, including the Plaintiff in particular.

121. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of use of Zimmer NexGen Knees was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and/or her physicians, hospitals and/or healthcare providers into reliance, continued use of Zimmer NexGen Knees, and actions thereon, and to cause them to purchase, recommend, and/or dispense Zimmer NexGen Knees and/or use the products.

122. Defendants knew that Plaintiff and/or her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Zimmer NexGen Knees, as set forth herein.

123. Plaintiff, as well as her doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

124. By reason of the foregoing Plaintiff ELSIE ALICE BUEHLER has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, severe pain, mechanical loosening and/or knee revision surgery, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

125. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses.

126. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**SEVENTH CAUSE OF ACTION  
AS AGAINST ALL DEFENDANTS  
(NEGLIGENT MISREPRESENTATION)**

127. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

128. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and/or the public in general that said Zimmer NexGen Knees, had been tested and found to be safe and effective for their intended use.

129. The representations made by Defendants were, in fact, false.

130. Defendants failed to exercise ordinary care in the representation of the Zimmer NexGen Knees, while involved in their manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce, in that Defendants negligently misrepresented Zimmer NexGen Knees' high risk of unreasonable, dangerous side effects.

131. Defendants breached their duty in representing the Zimmer NexGen Knees' serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and/or the public in general.

132. By reason of the foregoing Plaintiff ELSIE ALICE BUEHLER has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, severe pain, mechanical loosening and/or knee revision surgery, as well as other severe and



personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

133. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

134. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**EIGHTH CAUSE OF ACTION  
AS AGAINST ALL DEFENDANTS  
(FRAUD AND DECEIT)**

135. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

136. Defendants conducted research and used the Zimmer NexGen Knees as part of their research.

137. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, her doctors, hospitals, healthcare professionals, and/or the FDA that the Zimmer NexGen Knees were safe for their intended use.

138. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

139. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as her healthcare providers and/or the FDA.

140. The information distributed to the public, the FDA, and the Plaintiff by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

141. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' Zimmer NexGen Knees were safe for their intended use.

142. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' Zimmer NexGen Knees carried the same risks, hazards, and/or dangers as other available artificial knees.

143. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included false representations that the Zimmer NexGen Knees were not injurious to the health and/or safety of its intended users.

144. These representations were all false and misleading.

145. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that the Zimmer NexGen Knees were not safe and/or were not as safe as other available artificial knees.

146. Defendants intentionally made material representations to the FDA and/or the public, including the medical profession, and the Plaintiff regarding the safety of the Zimmer NexGen Knees, specifically but not limited to the Zimmer NexGen Knees not having dangerous and serious health and/or safety concerns.

147. Defendants intentionally made material representations to the FDA and/or the public in general, including the medical profession, and the Plaintiff regarding the safety of the Zimmer NexGen Knees.

148. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff to falsely ensure the quality and fitness for use of the Zimmer NexGen Knees and induce the public, and/or the Plaintiff to purchase, request, dispense, recommend, implant and/or continue to use said products.

149. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that the Zimmer NexGen Knees were fit and safe.

150. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that the Zimmer NexGen Knees were fit and safe and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other available artificial knees.

151. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that the Zimmer NexGen Knees did not present serious health and/or safety risks.

152. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that the Zimmer NexGen Knees did not present health and/or safety risks greater than other artificial knees.

153. That these representations were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

154. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, her healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her healthcare professionals to rely upon misrepresentations and caused the Plaintiff and/or her healthcare professionals to purchase, use, rely on, request, dispense, and/or recommend the Zimmer NexGen Knees.

155. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of the Zimmer NexGen Knees to the public at large, including the Plaintiff, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives.

156. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of the Zimmer NexGen Knees by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of the Zimmer NexGen Knees.

157. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her healthcare professionals, into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on the Zimmer NexGen

Knees and/or that her healthcare providers would dispense, implant, and/or recommend the same.

158. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as her healthcare professionals would rely upon the information being disseminated.

159. Defendants utilized direct to consumer advertising to market, promote, and/or advertise the Zimmer NexGen Knees.

160. That the Plaintiff and/or her healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as their superior knowledge and was thereby induced to purchase, use and rely on Defendants' Zimmer NexGen Knees.

161. That at the time the representations were made, the Plaintiff and/or her healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of the Zimmer NexGen Knees.

162. That the Plaintiff did not discover the dangerous and serious health and/or safety concerns and the false representations of Defendants nor could the Plaintiff, with reasonable diligence, have discovered the true facts.

163. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of the Zimmer NexGen Knees, Plaintiff would not have purchased, used and/or relied on Defendants' Zimmer NexGen Knees.

164. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

165. By reason of the foregoing Plaintiff ELSIE ALICE BUEHLER has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, severe pain, mechanical loosening and/or knee revision surgery, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

166. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

167. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00)

### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;
2. For any other causes of action and/or claims as may be compensable under local laws and/or statutes as may apply under the laws in the jurisdiction and venue in which this case will be transferred for trial;

3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;
4. Awarding Plaintiff reasonable attorney's fees;
5. Awarding Plaintiff the costs of these proceedings; and
6. Such other and further relief as this Court deems just and proper.

Dated: June 3, 2011

**SCHLICHTER BOGARD & DENTON**

By: /s/ Roger C. Denton

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**DEMAND FOR JURY TRIAL**

Plaintiff hereby demands trial by jury as to all issues.

Roger C. Denton  
ROGER DENTON

